Effect and working mechanisms of horseback riding therapy on motor function and daily activities of children with cerebral palsy. A feasibility study.

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The primary aim of the study is to investigate the feasibility of a RCT study on effectivity and workingmechanisms of HRT in children with CP. The Doel van deze studie is ten eerste de feasiblity onderzoeken van een toekomstige RCT study over het...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and peripartum neurological conditions
Study type	Interventional

Summary

ID

NL-OMON37836

Source
ToetsingOnline

Brief title
Horseback riding therapy in children with cerebral palsy.

Condition

- Congenital and peripartum neurological conditions

Synonym
Cerebral palsy, spastic children

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Stichting ZorgPKs en Stichting Beatrixoord Noord Nederland

Intervention

Keyword: Cerebral Palsy, Contents of therapy, Feasibility study, Horseback riding therapy

Outcome measures

Primary outcome

Feasibility of combination of measurements: gross motor function (primary outcome RCT), daily function, self confidence and quality of life (secundary outcome measures), spasticity and postural control during a daily activity, i.e. reaching, and quantitative analysis of video recordings of HRT-sessions (workingmechanisms).

Secondary outcome

Describe systematically contents of HRT-intervention.

Study description

Background summary

Children with cerebraly palsy (CP) more often have problems in daily life activities such as mobility, self care and social function than typically developing peers. Dysfunctional postural control plays a prominent role in these problems, possibly in concert with or mediated by spasticity. Horseback riding therapy (HRT) is one of the therapies applied in children with CP to improve daily life activities supposedly by means of reducing spasticity and improving postural control. Various studies on HRT have been published, but due to lack of rigour of the studies evidence on effectivity of HRT in children with CP is still lacking. Also workingmechanisms are unclear, e.g. the role of spasticity is uncertain.

Study objective

The primary aim of the study is to investigate the feasibility of a RCT study on effectivity and workingmechanisms of HRT in children with CP. The Doel van

deze studie is ten eerste de feasiblity onderzoeken van een toekomstige RCT study over het effect en de werkingsmechanismen van HRT bij kinderen met CP. The secundary aim of the study is to describe the contents of the HRT-intervention.

Study design

Feasibility study. Case study, with 6 cases and 3 repeated measurements (T0, T1, T2). AB-design, i.e., an A fase without HRT and a B fase with HRT. T0: 6 weeks prior to onset of HRT. T1: immediately prior to onset of HRT. T2: immediately after 6 weeks of HRT (2x/week).

Intervention

The children receive 2x/week 1 hour of HRT for a period of 6 weeks. Regular therapy will be continued.

Study burden and risks

The study is not associated with risks. The burden of the study consists of HRT (which children with CP generally enjoy), 3x asssessment of motor function (±20-30 min), 2x child friendly surface EMG assessment (±45 min, T1 en T2), 3x 2 mini-questionnaires for the child (±2 min), 3x interview parents (±30-45 min).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Unilateral or bilateral cerebral palsy
- GMFCS level II-III
- 6-12 year

Exclusion criteria

- Evident dyskinesia
- History of selective dorsal rhizotomy
- Botulinum toxin therapy during preceding 6 months
- Orthopedic surgery during preceding last year.
- Non-optimaly regulated epilepsy, defined as presence of > 2 fits/week
- Learning disability interfering with comprehension of riding instructions
- Allergy for horses
- Fear for horses

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2012
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

Date:	21-03-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL39372.042.12